

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

| | | |
|--|---|--|
| Applicant's or agent's file reference 116056 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No. PCT/AU2003/001369 | International Filing Date (day/month/year) 16 October 2003 | Priority Date (day/month/year) 17 October 2002 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61N 1/05, 1/18, H01J 9/02, H01B 5/14 | | |
| Applicant COCHLEAR LIMITED et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of **6** sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☒ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
 - VI ☒ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

| | |
|---|--|
| Date of submission of the demand 13 February 2004 | Date of completion of the report 28 January 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer GREG POWELL Telephone No. (02) 6283 2308 |

1. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19.
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Examination Authority has found that there are different inventions in the independent claims as follows:

1. Claims 1, 24, 26 are directed to an electrically conducting lead including an electrically conductive element which is comprised of a plurality of layers of electrical conductors. It is considered that the electrically conductive element comprised of a plurality of layers of electrical conductors comprises a first "special technical feature".
2. Claims 27 and 28 are directed to an electrically conducting lead, and the lead when used in a tissue-stimulating prosthesis, wherein the lead has an undulating form for at least a portion of its length. It is considered that the lead having an undulating form for at least a portion of its length comprises a "second special technical feature".

Since the above-mentioned groups of claims do not share either of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-28 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-28 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-28 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

Claims 1-28 meet the criteria for novelty, inventive step and industrial applicability. The prior art published before the priority date does not disclose an electrically conducting lead where the lead is either composed of a plurality of stacked conductors, or is composed of at least two wires having an undulating form in one direction.

With regard to the document listed in Box VI under "certain documents cited", this is a document published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

| Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|---|--------------------------------------|---------------------------------|--|
| P, X WO 2002/089907 | 14 November 2002 | 7 May 2002 | 7 May 2001 |
| <p>This document discloses an electrical conductor which is composed of a stack of a plurality of conductors. It is mentioned that this is a very flexible arrangement. It is common general knowledge in the art that leads can be made with conductors helically wound in an insulative body (see WO 1983/004182 for example). Replacing the leads in these prior art arrangements with the conductor disclosed in the above document would immediately suggest itself to the person skilled in the art. Therefore, claims 1-26 lack an inventive step.</p> | | | |

2. Non-written disclosures (Rule 70.9)

| Kind of non-written disclosure | Date of non-written disclosure (day/month/year) | Date of written disclosure referring to non-written disclosure (day/month/year) |
|--------------------------------|--|---|
| | | |

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 15 is not supported by the description. It purports to define a method of manufacturing the lead of claim 1, but only includes the step of winding a conductive element around an insulative body. This one step would not create the lead of claim 1.

More specifically, there is no limitation to the type of conductive element being wound. It is clear that this element must be composed of a plurality of layers of electrical conductors. Furthermore, the lead of claim 1 has the conductive element extending through (i.e. inside) the insulative body. Winding the element around the body does not place it inside the body. In addition, the different conductors of claim 1 are supposed to have the same longitudinal extent. This is achieved in the present application by either winding the element clockwise for the first half of the lead and then anti-clockwise for the other half, or by twisting the element halfway through the wind. This limitation is not present.

2. Claim 27 is not clear. It defines the lead as having a wire set which extends "across the set" in a first direction and then defines ridges and troughs extending "across the set" at angle to the first direction. The dual use (and apparent double meaning) of "across the set" is confusing. It would appear that this claim is meant to define that the wires of each set extend longitudinally in a first direction, and that the ridges and troughs are alternately formed along the longitudinal extent of the wires, but that they extend at an angle to the longitudinal direction, or something similar. However, this does not come out clearly.